

FORM CT-11

(See rules 53, 54, 55, 56, 57 and 58)

**PERMISSION TO MANUFACTURE NEW DRUG OR INVESTIGATIONAL NEW DRUG FOR
CLINICAL TRIAL, BIOAVAILABILITY OR BIOEQUIVALENCE STUDY OR FOR
EXAMINATION, TEST AND ANALYSIS**

Licence Number: CT11/BIO/22/000092

The Central Licencing Authority hereby grant permission to M/s Serum Institute of India Pvt., Ltd., 212/2, Off. Soli Poonawalla Road, Hadapsar Pune (India) – 411028 Telephone No.: 020-26602113, 26602378, 26602978 FAX: 020-26993945, 26993921 to manufacture the new drug or investigational new drug **for conduct of clinical trial** ~~or bioavailability or bioequivalence study~~ **as per protocol number dated SII-wHEXA/IN-03, Protocol Version 1.0 Dated 08 Jan 2021** in the below mentioned clinical trial sites ~~or bioavailability and bioequivalence study centre~~ [As per Annexure] ~~or for examination, test and analysis.~~

S. No.	Name of the new drug or Investigational new drug to be manufactured.	Class of new drug or investigational new drug	Quantity to be manufactured
1.	Each Single dose of 0.5 mL of vaccine contains: Diphtheria Toxoid20Lf Tetanus Toxoid.....4 Lf <i>B. Pertussis</i> 14 IOU Hepatitis B Protein..... 15 mcg Hib Polysaccharide (PRP) conjugate.....10 mcg IPV Type- 1.....20 DU IPV Type- 2.....4 DU IPV Type- 3.....16 DU Aluminum Phosphate as Al ³⁺0.28 mg 2 – Phenoxyethanol.....0.5% Sodium Chloride.....0.9%	Vaccine	28235 vials per batch

- This licence is subject to the conditions specified in the Chapter VIII of New Drugs and Clinical Trials Rules, 2019 under the Drugs and Cosmetics Act, 1940.
- This licence shall, unless previously suspended or revoked, be in force for a period of three years from the date of its issuance.
- Details of manufacturer and manufacturing site under this licence.

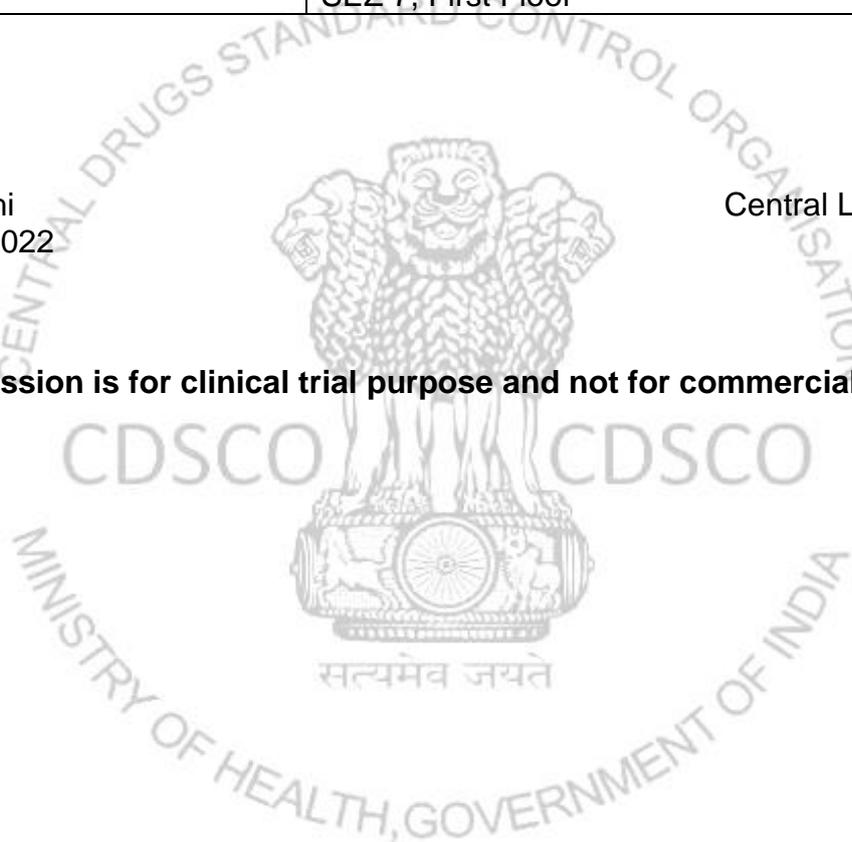
S. No.	Name and address of manufacturer (Full address with telephone, fax and e-mail address of the manufacturer).	Name and address of manufacturing site (full address with telephone, fax and e-mail address of the manufacturing site).										
1.	M/s Serum Institute of India Pvt. Ltd., 212/2, Hadapsar, Pune, Maharashtra – 411 028 (India) CONTACT: 91-20-26993900 FAX: 91-20-26993921	<p>Drug substance: M/s Serum Institute of India Pvt. Ltd., 212/2, Hadapsar, Pune, Maharashtra – 411 028 (India) CONTACT: 91-20-26993900 FAX: 91-20-26993921</p> <table border="1"> <thead> <tr> <th>Component</th> <th>Mfg. site</th> </tr> </thead> <tbody> <tr> <td>Diphtheria Toxoid:</td> <td>Building No.6 First Floor</td> </tr> <tr> <td>Tetanus Toxoid:</td> <td>SEZ-5 Second floor and first floor. Building no. 7 First floor and Ground floor</td> </tr> <tr> <td><i>B. Pertussis</i>:</td> <td>SEZ 7, Second Floor</td> </tr> <tr> <td>Hepatitis B Protein</td> <td>Building No.6: First floor</td> </tr> </tbody> </table>	Component	Mfg. site	Diphtheria Toxoid:	Building No.6 First Floor	Tetanus Toxoid:	SEZ-5 Second floor and first floor. Building no. 7 First floor and Ground floor	<i>B. Pertussis</i> :	SEZ 7, Second Floor	Hepatitis B Protein	Building No.6: First floor
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<i>B. Pertussis</i> :	SEZ 7, Second Floor											
Hepatitis B Protein	Building No.6: First floor											

			& Recombinant DNA Products and Derivatives (RDPD) facility, Building No.6: First floor
	Hib Polysaccharide (PRP) conjugate	SEZ-1B, Second floor SEZ-3, First floor	
	IPV Type- 1, 2 & 3	Bilthoven Biologicals B.V. Antonie van Leeuwenhoeklaan 9 -13 3721 MA Bilthoven The Netherlands	
Drug Product: M/s Serum Institute of India Pvt. Ltd., 212/2, Hadapsar, Pune, Maharashtra – 411 028 (India) CONTACT: 91-20-26993900 FAX: 91-20-26993921 SEZ 7, First Floor			

Place: New Delhi
Date: 21-NOV-2022

Central Licensing Authority
Stamp

Note: The permission is for clinical trial purpose and not for commercial purposes.



Annexure: Details of clinical trial sites:

S. No.	Name and Address of Clinical Trial Site	Ethics Committee details	Name of Principal Investigator
1	KEM Hospital Research Centre, Vadu Rural Health Program, Vadu Budruk, Taluka- Shirur, District Pune - 412216, Maharashtra, India	KEM Hospital Research Centre Ethics Committee, Sardar Moodliar Road, Rasta Peth. Pune-411011, Maharashtra, India (EC Registration no.: ECR/272/Inst/MH/2013/RR-19)	Dr. Anand Kawade
2	Institute of Child Health, 11, Dr. Biresh Guha Street, Kolkata-700017, West Bengal, India.	Institutional Ethics Committee, Institute of Child Health, 11, Dr. Biresh Guha Street, Kolkata-700017, West Bengal, India. (EC Registration no.: ECR/359/Inst/WB/2013/RR-19)	Dr. Kheya Ghosh Uttam
3	JSS Hospital, Mahatma Gandhi Road, Mysuru-570004, Karnataka, India	Institutional Ethics Committee, 3rd floor, JSS Medical College, S.S. Nagar, Mysuru-570015, Karnataka, India. (EC Registration no.: ECR/387/Inst/KA/2013/RR-19)	Dr. M. D. Ravi
4	Manipal Academy of Higher Education, Department of Community Medicine, Kasturba Medical College, Located at Dr. TMP Pai Hospital, Udipi- 576101 and Karkala-574104, Karnataka.	Manipal Academy of Higher Education Ethics Committee, Mezzanine floor, KMC Old Library Building, Madhava Nagar, Manipal-576104, Karnataka, India. (EC Registration no.: ECR/191/Inst/KL/2013/RR-19)	Dr. Veena Kamath
5	Baramati Hospital, Behind Kavivarya Moropant Natyamandir, Ring Road, Baramati, Pune-413102, Maharashtra, India.	Ethics Committee of Baramati Hospital Pvt. Ltd., Baramati Hospital, Behind Kavivarya Moropant Natyamandir, Ring Road, Baramati, Pune-413102, Maharashtra, India. (EC Registration no.: ECR/1449/Inst/MH/2020)	Dr. Bhaskar Jedhe Deshmukh
6	Hamdard Institute of Medical Sciences and Research (HIMSR) with Centre for health research & Development, Society for applied studies, Hakeem Abdul Hameed Centenary Hospital (HAHCH), Guru Ravidas Marg, Hamdard Nagar, New Delhi-110062, India	Jamia Hamdard Institutional Ethics Committee, Jamia Hamdard, Hamdard Nagar, New Delhi- 110062, India (EC Registration no.: ECR/48/Inst/DL/2013/RR-19)	Dr. Aparna Chakravarty
7	Government Medical College & Hospital, Medical College Square Road, Nagpur-440003, Maharashtra, India.	Institutional Ethics Committee, Government Medical College & Hospital, Medical College Square Road, Nagpur-440003,	Dr. Avinash Gawande

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		Maharashtra, India. (EC Registration no.: ECR/43/Inst/MH/2013/RR-19)	
8	PCMC'S Post Graduate Institute, Yashwantrao Chavan Memorial Hospital, Sant Tukaram Nagar, Pimpri, Pune-411018, Maharashtra, India	Institutional Ethics Committee, Yashwantrao Chavan Memorial Hospital, Sant Tukaram Nagar, Pimpri, Pune-411018, Maharashtra, India. (EC Registration no.: ECR/1236/Inst/MH/2019)	Dr. Deepali Ambike
9	Sri Ramchandra Institute of Higher Education & Research (DU), Clinical Research Division, Dental College Basement, No.1, Ramchandra Nagar, Porur, Chennai-600116, Tamil Nadu, India.	Institutional Ethics Committee SRIHER, Sri Ramchandra 1, Ramchandra Nagar, Porur, Chennai-600116, Tamil Nadu, India. (EC Registration no.: ECR/203/Inst/TN/2013/RR-19)	Dr. P. Umapathy



File No: BIO/CT/21/000046
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organization
(Biological Division)

FORM CT-06
(See rules 22, 25, 26, 29 and 30)

**PERMISSION TO CONDUCT CLINICAL TRIAL OF NEW DRUG OR INVESTIGATIONAL
NEW DRUG**

The Central Licensing Authority hereby permits M/s Serum Institute of India Pvt. Ltd. (SIPL), 212/2, Off Soli Poonawalla Road, Hadapsar, Pune -411028, India. Tel: 020- 26602113, 26602378, FAX: 020-26993945, 26993921. E-Mail: michael.vernekar@seruminstitute.com to conduct clinical trial of the new drug or investigational new drug as per **Protocol No.: Protocol No. SII-wHEXA/IN-03, Protocol Version 1.0 Dated 08 Jan 2021** in the below mentioned clinical trial sites.

CT No.: CT-25/2022

2. Details of new drug or investigational new drug and clinical trial sites [As per Annexure].
3. This permission is subject to the conditions prescribed in part A of Chapter V of the New Drugs and Clinical Trials Rules, 2019 under the Drugs and Cosmetics Act, 1940.
4. It may kindly be noted that merely granting permission to conduct Clinical trial with the vaccine does not convey or imply that, based on the Clinical trial data generated with the vaccine, permission to market this vaccine in the country will automatically be granted to you.

Place: New Delhi
Date: 21.11.2022

(Dr. V. G. Somani)
Drugs Controller General (India)
Central Licencing Authority

Annexure:**Details of New Drug or Investigational New Drug:**

Name of the new drug or investigational new drug:	Typhoid Conjugate Vaccine (Bivalent)	
Therapeutic class:	Vaccine	
Dosage form:	Solution for injection (Intramuscular)	
Composition:	Each dose of 0.5 mL Vaccine contains:	
	Ingredient	Quantity
	Diphtheria Toxoid	≥ 30 IU
	Tetanus Toxoid	≥ 40 IU
	<i>B. pertussis</i> (Whole cell)	≥ 4 IU
	HBsAg (rDNA)	≥10 mcg
	Inactivated Polio Vaccine (Salk strains grown on vero cells) Type -1	20 DU
	Inactivated Polio Vaccine (Salk strains grown on vero cells) Type -2	4 DU
	Inactivated Polio Vaccine (Salk strains grown on vero cells) Type -3	16 DU
	Hib conjugate (PRP-TT)	10 mcg
	Aluminium content Al ⁺⁺⁺ (As Aluminium Phosphate gel)	0.28 mg
	2-Phenoxyethanol	0.5 %
Sodium Chloride	0.9%	
Indications:	for active immunization for prevention of Typhoid Fever and Paratyphoid A Fever	

Details of clinical trial sites-

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3	JSS Hospital, Mahatma Gandhi Road, Mysuru-570004, Karnataka, India	Institutional Ethics Committee, 3rd floor, JSS Medical College, S.S. Nagar, Mysuru-570015, Karnataka, India. (EC Registration no.: ECR/387/Inst/KA/2013/RR-19)	Dr. M. D. Ravi
4	Manipal Academy of Higher Education, Department of Community	Manipal Academy of Higher Education Ethics Committee, Mezzanine floor, KMC Old Library	Dr. Veena Kamath

File No: BIO/CT/21/000046

	Medicine, Kasturba Medical College, Located at Dr. TMP Pai Hospital, Udipi- 576101 and Karkala-574104, Karnataka.	Building, Madhava Nagar, Manipal-576104, Karnataka, India. (EC Registration no.: ECR/191/Inst/KL/2013/RR-19)	
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In addition to point 4, the permission is subject to following conditions:

- i. The clinical trial shall be conducted as per protocol titled "An Open label, Randomized, Active-controlled, Multi-centric Phase-III Study in Indian Infants to Assess the Immunogenicity and Safety of SIPL HEXAVALENT (DTwP-HepB-IPV-Hib) Vaccine

File No: BIO/CT/21/000046

Containing "Reduced Dose IPV in Comparison with SIIPL Pentavac SD (DTwP-HepB-Hib) + Poliovac (IPV) Vaccines, Administered as Separate Injections" Protocol No. SII-wHEXA/IN-03, Protocol Version 1.0 Dated 08 Jan 2021.

- ii. DSMB shall be constituted for assessment of safety data of clinical trial.
- iii. The formulation intended to be used in the clinical trial shall be manufactured under GMP conditions using validated procedures and shall have ongoing stability programme.
- iv. Firm is required to submit updated stability data (accelerated & real time) of Drug substances & Drug product and ensure its stability during clinical trial.
- v. Only CDL, Kasauli certified batches shall be used in the clinical trial.

Place: New Delhi
Date: 21.11.2022

(Dr. V. G. Somani)
Drugs Controller General (India)
Central Licencing Authority